UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/580,893	05/30/2000	Lawrence B. Sandberg	25812-14	2093

21130 7590 09/10/2003

BENESCH, FRIEDLANDER, COPLAN & ARONOFF LLP
ATTN: IP DEPARTMENT DOCKET CLERK
2300 BP TOWER
200 PUBLIC SQUARE
CLEVELAND, OH 44114

EXAMINER	
GUPTA, ANISH	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/580,893	LAWRENCE B. SANDBERG ET AL.	
	Examiner	Art Unit	
	Anish Gupta	1654	

-- Th MAILING DATE of this communication appears on the cover sh et with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 15-20* is/are rejected.

7)☒ Claim(s) *13 and 14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 1-11 and 15-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the composition is composed of a "peptide or biological equivalent thereof." However, it is unclear what modified peptides and/or other compounds qualify as a "biological equivalent" of the peptide. The specification does not define biological equivalents and therefore, it is unclear what modification, such as amino acid deletions, addition and/or substitutions are permissible to render a peptide or other compounds biological equivalent.

Written Description

2. Claims 1-11 and 15-20 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not

sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

In the instant case, the claims are drawn to peptides that have activity in enhancing elasticity of tissue. The claims, no only claims peptide of SEQ ID 55-65, but also claim "biological equivalents" of these sequences. This generic statement "biological equivalent" of the peptide fails to adequately describe a structural feature common to the genus since the only common feature would be an amide bond between the amino acids. Further, the polypeptide and proteins of the claims are not limited to any specific class of compounds for which one could readily obtain physical and/or chemical properties or functional characteristics thereby obtaining some insight as to the structure of the desired proteins or polypeptide. The specification does not provide any guidance (emphasis added) as to the modification or structural differences needed in the peptides of SEQ ID 55-65 that would qualify as "biological equivalent." The specification, as a whole, does not sufficiently provide ample definition, such as by structure, formula, or chemical name, of the claimed subject matter sufficient to distinguish it from other peptides. Accordingly, the disclosure lacks sufficient written description to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

As stated earlier, the MPEP states that written description for a genus can be achieved by a representative number of species within a broad generic. It is unquestionable claim 1 is a broad generic with numerous variants for biological equivalent since includes any peptide that is "useful in treating a condition of mammalian tissue." (See claim 1). The number of amino acids can vary since the claim does not recite an amino acid length for biological equivalent. It must not be forgotten that the MPEP states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. Here, though the written description because there is no disclosure of a correlation between function and structure of the sequence. Moreover, the specification lack sufficient variety of species to reflect this variance in the genus since the specification does not provide any examples of peptides that are biological equivalents. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, it is deemed that the specification fails to provide adequate written description for the genus of the claims and does not reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the entire scope of the claimed invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-11 and 15-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Mitts et al. (WO00/28996).

The claims are drawn to peptides or biological equivalents thereof that are useful in enhancing tissue elasticity.

The reference discloses peptides that enhance "softness, elasticity, or appearance of tissue" (see abstract). The peptide disclosed by the reference include VVPG, VVPA, VVPQ and the like (see page 18-19 and claim 24). The reference teaches that the peptides are elastin peptide fragments (see page 17). The reference discloses topical formulations such as cosmetic preparation, powder, emulsion, lotion, spray ointment aerosol, cream and foam (see claim 29 and page 21 of the reference). Note that these are the same preparation as claimed in the instant application in claim 3-5. The reference also discloses that the peptides are used in a concentration between .0002% to 90%, similar to claim 2 of the application (see page 20 of the reference). The reference discloses pharmaceutical delivery system that is inclusive of both topical and subcutaneous delivery of the peptide. Finally, the reference discloses that the peptide is effective in enhancing elasticity of the skin, blood vessel, and lung tissue, similar to claim 18 of the instant application (see page 13 and page 23). Although the reference does not teach a peptide have the sequence of SEQ ID 55-65, the reference still anticipates the claimed invention because the disclosed peptides would qualify as

"biological equivalents." This is because the disclosed peptides are elastin fragments and are effective in enhancing tissue elasticity of the skin, lung or blood vessel similar to the instant application. Further note that the peptides of the reference differ from the peptide of the claimed (SEQ ID 55, VVPN) invention by a single amino acid. Thus, the peptides of the reference are "biological equivalents."

4. Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Hedrick et al. (WO 98/47921).

The claim is drawn to a peptide of the formula R1-Valine-Valine-Proline-Asparagine-R2, wherein R1 can be an amino acid sequence having 1-10 amino acids and R2 is carboxyl portion of the sequence.

The reference discloses the peptide Ile-Ser-Val-Val-Pro –Asn. (See claim 1, page 99, line 12). Note that this peptide anticipates the claim since the Ile-Ser qualifies under R1 as an amino acid sequence of less then 10 amino acid and R2 is the carboxyl terminus. The core peptide is Valine-Valine-Proline-Asparagine.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 1-11 and 15-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-16 of U.S. Patent No. 6,069,129. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons.

The claims are drawn to peptides or biological equivalents thereof that are useful in enhancing tissue elasticity.

The US Patent claims peptides that enhance tissue elasticity, similar to claim 1 and 15 of the instant application (see claim 1 and 13 of the US Patent). The US Patent claims a peptide of the sequence VVPQ (see claim 1, 18, and 27). The reference discloses topical formulations such as cosmetic preparation, powder, emulsion, lotion, spray ointment aerosol, cream and foam (see claims 7-10, 14-17). Note that these are the same preparation as claimed in the instant application in claim 3-5. The reference also discloses that the peptides are used in a concentration between .0002% to 90%, similar to claim 2 of the application (see claim 5 of the US Patent). The reference discloses pharmaceutical delivery system that is inclusive of both topical and subcutaneous delivery of the peptide (see claims 15-16). Finally, the reference discloses that the peptide is effective in enhancing elasticity of the skin, blood vessel, and lung tissue, similar to claim 18 of the instant application (see claims 18-26 of the US Patent.) Although the reference does not teach a peptide have the sequence of SEQ ID 55-65, the reference still anticipates the claimed invention because the disclosed peptides would qualify as "biological equivalents." Note that the peptide of the US Patent differs from the claimed peptide of SEQ ID 55, by one amino acid. Further, since the US Patent claims that the peptide is effective in enhancing tissue elasticity of the skin, lung or blood vessel similar to the

instant application, the peptide would qualify as a "biological equivalent". Thus, the US Patent and the instant claimed invention are not patentably distinct from each other.

6. Claims 13-14 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The prior art does not teach nor fairly suggest the peptide of sequence VVPN and CVVPNC. Therefore the sequences are allowable over the prior art of record.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (703) 308-4001. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback , can normally be reached on (703)306-3220. The fax phone number of this group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Anish Gupta
Patent Examiner
September 8, 2003